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Activity Report 2009 of the European Union Reference Laboratory for Food Contact Materials

SANCO/2008/FOODSAFETY/0055-Contact Materials
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ihcp Institute for Health and Consumer Protection

The mission of the JRC-IHCP is to protect the interests and health of the consumer in the framework of EU legislation on chemicals, food, and consumer products by providing scientific and technical support including risk-benefit assessment and analysis of traceability.

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Executive summary

The following report is a technical report mostly destined to Commission services, National Reference Laboratories and Member State Competent Authorities. It reports the 2009 update of the deliverables from the work programme 2009 of the Community Reference Laboratories for Food Contact Materials established under Regulation EC No 882/2004. The deliverables are established based on the responsibilities of the EURL laid out in Article 32, as follows:

Article 32 - EURLs (referred to in Annex VII) shall be responsible for:

(a) Providing national reference laboratories (NRLs) with details of analytical methods, including reference methods;

(b) coordinating application by the national reference laboratories of the methods referred to in (a), in particular by organizing comparative testing and by ensuring an appropriate follow-up of such comparative testing in accordance with internationally accepted protocols, when available;

(c) Coordinating, within their area of competence, practical arrangements needed to apply new analytical methods and informing national reference laboratories of advances in this field;

(d) Conducting initial and further training courses for the benefit of staff from national reference laboratories and of experts from developing countries;

(e) Providing scientific and technical assistance to the Commission, especially in cases where Member States contest the results of analyses;

The 2009 annual work programme of the EURL included 2 core areas. These objectives and the main achievements are described below:

Core Area 1: Methodologies for sampling and analysis

Activity area 1a – methods of analysis protocols (Art 32 1(a))

The database on methods of analysis was expanded to include the methods provided by applicants when requesting an authorisation for a substance. The descriptions for 2009 amounted to 70 method summaries which corresponded to 54 substances. A compilation was created for all substances in the database in 3 volumes.

Activity area 1b – reliability of results & comparative testing (Art 32 1(b))

1b-1 Guidance documents

1b-1.1 Development of guidelines on method performance and validation

Following the workshops organised in 2008 the first edition of the guidelines on method performance and validation was completed. The document was published (EUR 24105 EN, 2009) and is publicly available on the EURL website.

1b-1.2 Development of guidelines on sampling and testing conditions

Following the workshops organised in 2008 a first edition of the "guidelines on testing conditions for articles in contact with foodstuffs (with a focus on kitchenware) was completed. The document was published (EUR 23814 EN, 2009) and is publicly available on the EURL website.

1b-1.3 Development of guidelines on the practical implementation of the 4th amendment of Directive 2002/72/EC

Two workshops were organised to continue the development of the guidelines on the practical implementation of the 4th amendment of Directive 2002/72/EC in the context of official controls. The items selected for these guidance documents were: Primary Aromatic

Amines (PAAs), phthalates, Fat Reduction Factor (FRF) and Functional Barrier. A table on short guidance on phthalates was completed, a calculation example for PAAs was prepared and a short guidance on functional barriers was also completed. A flowchart on the use of various correction factors of the experimental migration was developed. An Excel spreadsheet was developed for the direct comparison of the experimental migration with the specific migration limit (SML) of the substance. A guidance on the use of the flowchart and spreadsheet is now in preparation. The respective deliverables can be found on the Circa JRC-EURL-FCM website.

1b-2 Comparative testing, ring trials, etc.

Two validation studies for a) Di-isodecyl phthalate (DIDP) in oil and b) Bisphenol A (BPA) in the new milk simulant 50% Ethanol were organised and completed successfully. Their respective reports are on the Circa JRC-EURL-FCM website[1].

1b-3 Collection of reference monomers and additives

When requesting an authorisation, applicants are requested in the EFSA guidelines to send a sample of the substance to the JRC. The JRC then includes those substances in their reference collection. During 2009, 19 samples were received and classified into the databank with their information.

1c emerging issues

In agreement with DG SANCO the EURL initiated ad-hoc work in 2009 to support the Commission in the ongoing discussion on Plastic Implementing Measures and in particular on the revision of Community Guidelines for Migration Testing (also under point 2.1.4 of the Annual Work Program). This item substituted meetings allocated for the work of the working group on active and intelligent packaging (AIM). Consequently the continuation of the work on AIM was postponed to 2010 or to when the support to PIM will no longer be required.

1d Training

Several trainings were organised by the EURL upon request, including for the FVO on April 29-30 2009 and for a representative of the Consumer Products Testing Laboratory of Vietnam on June 22-26. A request from the National Agency for Drug and Food Control of Indonesia was received but due to Visa issues delay on the Indonesian side, the training was postponed to 2010.

Core 2:	General tasks and support to Commission

Operational procedures

The plenary and workshops meetings were organised as planned and the reports were submitted timely and can be found on the JRC-EURL-FCM Circa website.

Technical and scientific support to Commission

At the beginning of the year SANCO agreed with the EURL to create a dedicated expert group in order to support the Commission in the ongoing discussion on Plastic Implementing Measures and in particular on the revision of Community Guidelines for Migration Testing (point 2.1.4 of the Annual Work Programme).

Ad-hoc expert workshops were held on 1-2 April 2009, 29-30 June, 05-06 October to discuss and brainstorm the drafting of the DG SANCO Community Guidelines on migration testing in the context of the recast of the plastics directives into a Plastics Implementing Measure (PIM).

Two versions of the Guidelines were produced and also presented when needed to Member State Competent Authorities during DG SANCO FCM working party meetings.

[1]: http://circa.europa.eu/Members/irc/jrc/jrcEURLfcm/library

Table of contents

Core Area 1: Methodologies for sampling and analysis

Activity area 1a – methods of analysis protocols (Art 32 1(a))

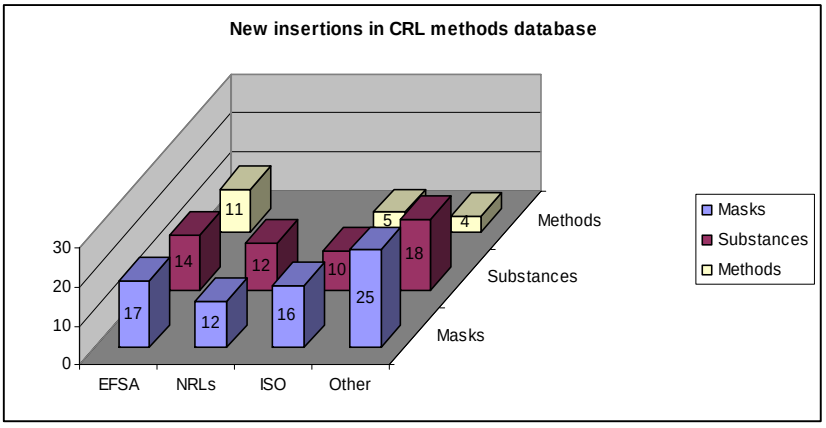
Type of work item:
Continuous –yearly

Objective:
To expand the data bank containing methodologies for the analysis of plastic food contact materials monomers and additives and expand this data bank to other types of materials.

Planned deliverable:
Report / CD-ROM of at least 40 additional methods from literature or other sources and make their technical specification publicly available via the Method Databank.

Summary 2009

During 2009, the database of methods was enriched with 70 new method summaries (referred to as "masks" on the graphs). These method summaries were related to 54 different substances.



1a-1: EFSA: methods that were submitted to EFSA and for which an opinion was published in 2009 were included in the databank. This amounted to data for 17 method summaries;

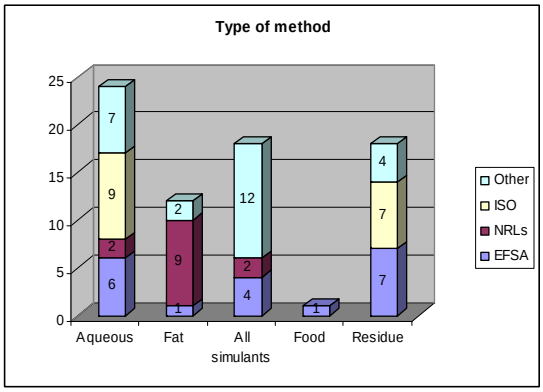
1a-2: NRLs: National Reference Laboratories sent data for the preparation of 12 method summaries;

1a-3: Other sources (including ISO): ISO standards were the source for 16 method summaries and 25 method summaries were prepared using data from other sources (literature, old petitioners' dossiers, etc.).

In addition, 20 additional full descriptions of analytical methods in an anonymous format were prepared for the EURL database.

The methods were of different types, as follows:

- 24 were developed for aqueous simulants,
- 12 developed for fat simulants,
- 18 were suitable for all simulants,
- 1 was developed for food analyses,
- 18 were developed for residue analyses.



1a-4: Sensory: A literature up to 2009 was collected on sensory analysis which comprised 40 articles; some were related to shelf life or to packaging or to foods (related to a preservation or process). The original articles were obtained and are stored at the EURL to be made available. The list will be available in May on the circa web site.

In the frame of the methods database, the EURL prepared a compilation of methods to detect migrants from food contact materials. These methods could be European standards, validated methods or simple suggestions for laboratories that could find necessary to better develop them or to validate them. Three volumes were prepared, containing all the methods available in the JRC method database in anonymous format up to December 2009. At the end of each volume, the full list of the methods available in all the 3 first volumes is reported. It is presented both in Ref. and CAS order. In the first 3 volumes, one ore more methods (per residue, in simulants or in food) for 290 Ref. numbers and for 334 CAS numbers were reported. A more extensive summary table "all at a glance" table was also developed. These volumes will be published in May on the Circa JRC-EURL-FCM website.

Activity area 1b – reliability of results & comparative testing (Art 32 1(b))

Article 32 (1b) addresses comparability as the most important feature of the measurements of NRLs. The NRLs-FCM recognised that technical specifications are not always detailed in standards or legislative documents, and thus there is sometimes lack of harmonisation in how official controls are practically performed. Several guidelines were initiated and aim to empower NRLs to be able to give the same and competent advice in this field to National Authority, Food Inspection and compliance laboratories for the practical implementation of official controls for FCM.

1b-1 Guidance documents (methods, sampling, intepretation etc)

1b- 1.1 Guidelines on method performance (continuation of 2007-2008)

Type of work item:

large work item – project duration expected 3-4 years

Objective:

To establish consensus guidelines for method performance both for official controls and in general for the validation of methods, simplified schemes, and minimum quality criteria.

Planned milestones and deliverables

As milestones minimum of 2 task force meetings were foreseen as well as reporting and consultation at one plenary. The year 2009 had for specific aim to:

1) Provide a first deliverable with the publication of the 1st edition of the core of the guidelines, excluding all annexes and related further on-going work.
2) Focus on NRLs to test the guidelines on their own and provide the worked examples for the annexes.
3) Further investigation and testing of commercial softwares for method validation

Summary 2009

Upon completion of the workshops in 2008, it was decided that a first publication of the guidelines should occur in 2009 since the version resulting from 2008 was a version ready for edition / review and publication as 1st edition. It was agreed to a number of worked examples on a number of substances and types of applicable limits would be prepared for insertion in a second expanded edition to come in 2011. A number of NRLs volunteered to apply the guidelines on specific case studies of their own work. The strategy adopted of publishing the

1st edition (core) in 2009 was designed to allow making the much needed guidance publicly available while pro-actively preparing a strategic follow-up. 3 progressive versions of the document were produced: one pre-final version prior to editing by Mrs. Bradley (NRL-UK), the edited or commented version from NRL-UK and the integrated final version. The document was published (EUR 24105 EN, 2009) and is publicly available on the EURL website.

HIGHLIGHT!
Publication of the first harmonised guidelines for the validation and evaluation of method performance by the EURL-FCM in support to the implementation of Regulation 882/2004. (EUR 24105 EN -2009).

Article 32 (1b) of Regulation 882/2004 on official feed and food controls addresses comparability as the most important feature of the measurements of National Reference Laboratories. A fundamental step is the implementation of performance criteria and harmonization the evaluation of method performance, which was lacking for the field of FCM. These guidelines represent a reference consensus for NRLs-FCM to better ensure harmonisation of official controls and are a major deliverable of the mandate of the EURL-FCM.

Two worked examples were collected from 2 NRLs in 2009 for insertion in the next edition.
The software for organisation and interpretation of data from ILCs was discussed with colleagues from IRMM on 20.04.2009 and it was agreed with CRL-PAHS and CRL-Mycotoxins to maintain and expand the harmonisation of the use of the software ProLab plus. In that perspective a common training was organized in the IRMM on February 15-18 2010.

1b-1.2 Guidelines on sampling, test conditions with an emphasis on articles to be placed in contact with food for home use (continuation of 2007-2008)

Type of work item:
large work item – project duration expected 3-4 years

Objective:

Develop unified reference consensus guidelines for NRLs on test conditions for food contact articles such as kitchenware, where Rapid Alerts have shown differences in enforcement protocols.

Planned milestones and deliverables:
The milestones included a minimum of 2 task force meetings – reporting and consultation at the 2 plenaries., with further indications of worked examples where needed and planning for new revisions of the guidelines (towards new developments emerging for the recast of test conditions in a new legislation)

Summary 2009

The version resulting from the December 2009 workshop was considered a version ready for edition / review and publication as 1st edition in 2009. The need for a rapid publication was emphasised due to the number of inquiries received showing the need to make this guidance public. It was agreed to keep working on other worked examples prepared for insertion in a second expanded edition to come in 2011. The strategy adopted of publishing the 1st edition (core) in 2009 was designed to allow making the much needed guidance publicly available while pro-actively preparing a strategic follow-up. 3 progressive versions of the document were produced: one pre-final version prior to editing by Mrs. Bradley (NRL-UK), the edited or commented version from NRL-UK and the integrated final version. The first edition of the "guidelines on testing conditions for articles in contact with foodstuffs (with a focus on kitchenware) was published (EUR 23814 EN, 2009) and is publicly available on the EURL website.

HIGHLIGHT!
Publication of the first Guidelines on test conditions for kitchenware by the EURL-FCM (EUR 23814 EN)

The harmonisation of test conditions are crucial to obtain reliable results for official controls. For plastic food packaging time/temperature conditions are specified in Directives, but kitchen articles are placed in contact with food in the home, and Rapid Alerts have shown differences in testing in enforcement protocols. The guidelines just published describe worst foreseeable test conditions for food contact articles such as kitchenware. They represent a reference consensus for NRLs to better ensure harmonisation of official controls and are a major deliverable of the mandate of the EURL-FCM.

1b-1.3 Guidelines on the practical implementation of the 4th amendment in the context of official controls (completion of work item 2008)

Type of work item:
Medium work item – project duration expected 1 year

Objective:
A guidance providing a practical common understanding and testing towards the limits in the text in the 4th amendment of Directive 2002/72 (published as Directive 2007/19/EC). In particular several items were selected as focus for guidance: phthalates, Fat Reduction Factor and Functional Barriers.

Planned milestones
The EURL developed and chaired a dedicated working group of NRLs to develop 3 specific guidelines towards the correct practical implementation of the 4th amendment of Directive 2002/72/EC. The EURL work programme 2009 called for a minimum of 2 workshops on "4th amendment" to be organised. The workshops focused on guidance on new requirements inserted in the plastics directive such as the use of fat reduction factors, the functional barrier concept, the analysis of certain plasticizers and Primary Aromatic Amines. The working group had three meetings for ½ day each in Ispra on 1 April 2009, Varese on 29 June 2009 and Ispra on 05 October. Detailed milestones can be found in Annex 1.

Summary 2009
The different guidelines targeted respectively:
1) A simplified table clarifying the restrictions of phthalates for different types of use and food matrices. This item was finalised in 2009.
2) A spreadsheet that compares the experimental migration with the SML while correcting for the Fat Reduction Factor (FRF) depending on the nature of the chemical. This item was extended by including also the food simulant D Reduction Factor (DRF) and the correction for the difference between experimental conditions and real food contact conditions. For a complete understanding of the Directive, a flowchart was developed, which was the basis for the spreadsheet. The flowchart and spreadsheet were finalised in 2009. A guidance document on how to use the flowchart and the spreadsheet is under development.
3) A short guidance on understanding the practical implications for showing compliance with the concept of functional barrier. This item was finalised in 2009.
4) A calculation example for showing compliance of Primary Aromatic Amines due to the changes of the 4th amendment. This item was finalised in 2009.

HIGHLIGHT!

An easy to use excel model for calculating the application of a "fat reduction factor" implemented in the plastics Directive 4th amendment of Directive 2002/72/EC into practical cases. The model was based on ranges of relevant foodstuffs established based on the data researched in the RTD Foodmigrosure project as well as physico-chemical information such as lipophilicity of substances.

1b-2 – comparative testings, ring trials etc.

Type of work item: medium work item – project duration expected 1 year

Development of work item (general scheme applicable to both interlaboratory exercises)

Partner	Tasks	Timeline
JRC	Technical consultation with NRLs to finalise technicalities of design (topic of investigation) Collaboration with stakeholders (industrial) for production of materials Production of adequate test samples	3 months
JRC	Develop Standard/standard mixture or solutions, experimental design for production of matrices Develop test samples (materials, solutions and or simulants) information and implementation of test methods	4 months
JRC	Homogeneity testing of test material(s) Material approval	2 months
JRC	Develop response templates. Preparation of results reporting and lab training Shipping of samples	2 months
JRC	Collection of results Statistical interpretation	2 months
JRC	Technical report	1 month

Objectives:

For 2009, the specific topics chosen in consensus in the EURL-NRL-FCM network were of at least one interlaboratory comparison (ILC) trial. At the time of the submission of the WP 2009, these targets had not been completely defined, since the final decision depended on the results of the proficiency testing that was still on going on epoxidised soybean oil (ESBO) and phthalates. The finalisation was made in the December 2008 plenary meeting upon discussion of the preliminary results of the trials. The exercises were:

- First ILC: validation of method for the quantification of Diisodecyl phthalate (DIDP) in oil
- Second ILC: validation of method for the quantification of Bisphenol A in the new milk simulant 50% Ethanol

1b-2.1 Laboratory exercise of validation of method for the quantification of DIDP in oil

The aim was to develop and perform the validation of a method for the analysis of DIDP (as model substance for a technical mixture of phthalates) from oil (as simulant for fatty foods). The strategy rose from the proficiency tests on plasticisers conducted by the EURL-FCM for the NRLs in 2008 (both in gaskets and in oil) that highlighted that the substances of lesser performance were technical mixtures of phthalates (DINP, DIDP) and it was decided to thus strategically deploy a follow up work item for 2009 with the development and validation of an improved method.

The EURL completed a preparation phase and distributed several spiked solvent and oil samples for the analysis of DIDP. This testing was used both as proficiency testing and to validate a standard operating procedure (SOP) for the determination of DIDP in oil that has been written by the EURL based on the most performant methods used by NRLs in the proficiency test of 2008. The homogeneity and stability studies were performed by the EURL-FCM laboratory. Testing was performed by the EURL and a final SOP sent to NRLs with the final documents and results templates for reporting. After homogeneity testing the lots of fortified oils were sent to the NRLs (see table of milestones). A deadline of 11 September was agreed to give ample time for tests including during the holiday period. Participation of local laboratories under NRLs was encouraged (by producing 60 samples). There were 27 participants to whom samples were dispatched 24 of which submitted results.

From the EURL-NRL network 22 laboratories out of 24 reported results. There were 2 guests from Germany that provided results as well. Participants were invited to report four replicates measurements under repeatability conditions. The ILC was closed permanently in the middle of October for statistical interpretation.

Based on the results in this precision experiment the method performance was assessed through evaluation of the repeatability and reproducibility standard deviation (SD) according to the mechanism described in ISO 5725. The assigned value and its uncertainty were obtained as a consensus values after applying the robust statistics to the results obtained from the participants. Laboratory results were rated with z and z' scores in accordance with ISO 13528. Standard deviations for proficiency assessment (also called target standard deviations) were set based on Horwitz equation. The participation of the laboratories was regarded as satisfactory for the aim of the precision experiment with regards of the numbers of received results thanks to the proactive involvement of the NRLs-FCM. As a conclusion for participation and laboratory performance, this ILC showed:

- A noted increase in participation compared to the similar exercise of 2008. The number of laboratories submitting results for DIDP in oil rose from 17 to 25. This was due in part from the experience acquired in the previous year exercise as well as to the provision by the EURL of both the method description in a CEN like format as well as of the internal standard.
- A great increase in laboratory performance compared to 2008 with 76-92% of successful achievement of results from the participants within the tolerance limits (range 76-92% depended on concentration level considered) compared to 59% in 2008. In particular the performance at the concentration level of the SML was 80% compared to 59% for the same exercise in 2008. The harmonisation of the procedure and following a harmonised method for determination of DIDP in oil in 2009 resulted in a decrease more then 2.5 times in the reproducibility SD from 37% to 14 % for the concentration level around SML of 9 mg/kg while the repeatability SD remained almost the same – 6.5%.

Detailed milestones can be found in Annex 2.

1b- 2.2 Laboratory exercise of validation of method for the quantification of Bisphenol A in the new milk simulant 50% Ethanol.

The general aim was to develop and perform the validation of a method for the analysis of Bisphenol A as model substance for a polycarbonate (PC) materials historically typically used as baby bottles and therefore typically in contact with mostly milk-type products. The strategy rose from the implementation of a new milk simulant 50% Ethanol (EtOH) that current CEN standards for specific migration have not addressed yet.

The first specific intention of the exercise on BPA was to validate an extension of scope of EN13130 Part 13 to be extended to include this new simulant 50% EtOH, i.e. the method for the quantification of BPA in 50% EtOH in the range around the legislative specific migration limit (SML). Another intention had been potentially foreseen in secondary phase to obtain polycarbonate test materials that release levels of Bisphenol A to levels around the SML to test the laboratories ability to perform the migration phase of the compliance test. The industry chain and professional associations readily collaborated but reported the absence of feasibility to produce PC releasing at the SML. The EURL thus asked for PC releasing at measurable levels. 3 batches were received as donations from industrial associations, and the EURL performed analyses that showed that all materials could only release Bisphenol A at levels only at the limit of quantification (LOQ) when tested using the conventional test conditions. A number of options were proposed by the EURL first by e-mail of the update May-June (7 answers received) and again during the plenary to cover all MS NRLs. It was agreed that for the 2009 programme the work would be to carry out the test on spiked 50% ethanol only. However rather than just validating the method at levels close to the SML (0.6 mg/kg) as required for compliance purposes and to provide the validation data for inclusion

in the CEN standard, it was agreed that a second validation range would also be studied to allow validation data to be generated for exposure purposes. In total four 50% ethanol solutions containing different concentrations of Bisphenol A were provided for analysis encompassing concentrations of relevance to exposure determination and compliance determination. The homogeneity and stability studies were performed by the EURL-FCM laboratory. Standard operating procedures (SOPs) for the two approaches were also written. The spiked samples and SOP(s) were sent in August and the deadline for the submission of results was mid-October. Participation of local laboratories under NRLs was encouraged (by producing 60 samples). There were 31 participants from twenty-five countries to whom samples were dispatched and 24 of which submitted results. From the EURL-NRL network 18 laboratories out of 24 reported results. There were 3 guests from Spain and 3 from Germany that provided results as well. Participants were invited to report four replicates measurements in repeatability conditions. This was done by most of the participants. The ILC was closed permanently in the end of October for statistical interpretation. The results of analyses were received and statistically interpreted. The assigned values were obtained as a consensus values after applying the robust statistics to the results obtained from the participants. Laboratory results were rated with z-scores in accordance with ISO 13528. Standard deviations for Interlaboratory comparison (also called target standard deviations) were set based on Horwitz equation and Horrat ratio 0.5. The results and preliminary report discussed in the plenary December 2009. The participation of the laboratories was regarded as satisfactory for the aim of the precision experiment with regards of the numbers of received results. Absolute minimum of participating laboratory for conducting a precision experiment was 8. Some of the NRLs communicated the lack of the possibility to follow exactly the method for BPA determination as they used different analytical technique (e.g. LC-MS instead of HPLC/FLD). Since the aim of the ILC was directed towards method validation there was a communication to the participants that different techniques were not fit to the scope of this ILC. That was the reason for slightly lower percent of reported test results as compared with the other ILC 2009. As a conclusion of the precision exercise on the quantification of Bisphenol A in the new milk simulant 50% ethanol, this ILC showed that:

- The participation in the ILC was satisfactory for the purpose of the study towards validation with 24 laboratories.
- The validation of the method based on HPLC-FLD according to the description based mostly on the previous CEN standard TS 13130-13 was successful with more than 8 valid results thanks to the proactive involvement of the NRLs.
- The precision that can be suggested are those listed as parameters in the table below

Concentration level (mg/kg)	Reproducibility (R), %	Horrat R	Repeatability (r), %
0.0067	15	0.7	**6**
0.021	10	0.4	**4**
0.075	6	0.3	**2**
0.56 (SML)	**6**	**0.3**	**0.8**

With respect to the scarcity of data previously available in the validation performed as reported in the CEN standard TS 13130-13 (issued version of 2005), this validation also provides a great breadth of valuable detailed and traceable raw data, which should prove extremely relevant for the creation of an extension of the standard from CEN.
Detailed milestones can be found in Annex 3.

1b-3 – Test materials, and substances, calibrants, reference materials

Objective:

To continue the set-up of the food contact materials monomers and additives substance databank (about 20 substances for which opinions are published per year on average)

Deliverable:

New substances in the substance collection, spectral (FT-IR and GC-MS) analyses and compilation of physico-chemical information; Compilation of data for the annual report

Summary 2009

In 2009 19 substances were received and classified with their compilation of information (physico-chemical and/or spectral). They were all inserted in the database and organised into the reference collection of monomers and additives that the JRC maintains since 1996.

Activity Area 1c - Emerging issues and methods (art. 32 1(c)): task force Active and Intelligent Materials

Objective

A specific working group was formed to gather information on the testing of active and intelligent packaging/materials (AIM) in support of Regulation (EC) No 450/2009. This work item will serve as basis to prepare a guidance document by a specific working group.

Planned milestone and deliverable

Working group on active packaging. 2 meetings – reporting at the plenaries.
Review of market, measures in place of foreseen, potential methods
Development of outline and structure of guidelines

Summary 2009

The year 2009 had a more restricted activity than foreseen with only one meeting due to the ad-hoc item taken on on request of DG SANCO related to tehncial contributions to the recast of the Plastics Directives. The ad-hoc item on PIM (see under point 2.1.4) committed 3 meetings and extensive time. It had therefore been agreed with DG SANCO that the AIM work was the one that was most amenable to time flexibility.
The meeting on active and intelligent materials (AIMs) took place on 06 October 2009. The aim of the meeting was to consider the AIM Regulation, EFSA guidelines and the TNO report on testing several AIMs, to raise any points that are not clear in these documents and to propose solutions to address them. Although a task force was set up on AIMs and articles in 2007 all NRLs were invited to participate in the discussion. In conclusion, the following working items were identified:

- Guidance on criteria for grouping substances according to their structure or toxicological behaviour, including examples
- Collection of any information on the use of nanotechnology in food contact materials and articles with particular reference to those that may be used as an active or intelligent function
- Guidance on which supporting documents should be provided by the manufacturers
- Guidance on the testing that should be carried out by the enforcement laboratories
- Creation of a database on test methods originating from EFSA application

Activity area 1d – Training (Art 32 1 d)

Training could be offered on the premises of the EURL for the following types of analyses:
Overall migration in oil and aqueous simulant (immersion, single face, pouch, filling)
Specific migration: in 2009 the EURL placed specific emphasis on analyses such as gaskets and foods in jars (e.g. multimultinalytes plasticisers), Bisphenol A, inks and benzophenone and derivatives, melamine from utensils, etc. The specific programmes were developed as a function of request and interests from the delegations (in or out of EU).

The trainings mentioned as examples in the work programme 2009 (NRL-Luxembourg, China and Thailand) were already completed at the end of 2008. In 2009, the requests completed are summarised in the table below.

Description	completed
Visit training of Tubitak (TK) at EURL-FCM A first training took place in the context of the SAFETechnoPACK (FP7-REGPOT-2007). This project deals with the implementation of technological and safety controls know-how on food contact materials in Turkey and was co-ordinated by the institute Tubitak MRC. JRC acts as mentoring and training facility. This was a milestone in participation in RTD projects and also in the practical implementation of the JRC collaboration agreement with Tubitak.	13.02.2009
Food and Veterinary Office inspectors training at the EURL-FCM for food contact materials The EURL-FCM gave special 2 day training to Food and Veterinary Office inspectors. This training requested by the FVO took place in preparation of upcoming missions to China, Vietnam and India. The training included overall migration and specific migration methods, as well as specific methods such as plasticisers from lids from glass jars, benzophenone from paper and board, formaldehyde/melamine from melamine ware, and primary aromatic amines from kitchen utensils.	29-30.04.2009
Training organised by EURL-FCM for Vietnamese delegation. The EURL-FCM hosted a dedicated training for a guest from the Consumer Products Testing Laboratory of Vietnam. The training focused on laboratory issues, including overall and specific migration, plasticizers, melamine, formaldehyde as well as migration modelling. The impact was a collaboration to solve FCM import-export issues, and a deliverable of the mandate EURL-FCM towards third country experts.	22-26.06.2009

Activity Area 1e- Technical and scientific support to Commission in case of disputes

In case of dispute the EURL would also perform analyses or provide help as best agreed between parties involved to help resolve the disputes.
None were received.

Core 2: General tasks

2.1 Operational procedures

2.1.1 Compilation of annual report and cost estimates

The signature of the administrative arrangement of EURL-FCM for 2009 was done on 21.01.2009.
The technical reports related to the different task forces of the EURL-NRL-FCM network, were submitted to DG SANCO (included method performance, test conditions, 4th amendment, AIM and Community Guidelines for migration testing), in the following dates: 29.01.2009, 27.02.2009, 26.05.2009, 15.07.2009, 20.11.2009 All were endorsed.
The annual report, deliverables and financial reports of the EURL-FCM were submitted to DG SANCO for the year 2008 on 30.03.2009 regarding the dedicated work programme of the EURL Food Contact Materials.
Technical Report of the plenaries were submitted respectively on 29.01.2009, 15.07. 2009, 10.01.2010 and the mid year report on 25.08.2009. The work programme and budget of the WP 2010 were submitted on 29.08.2009 to DG SANCO after discussion in the July EURL-FCM in July and a written consultation in August . WP and Budget 2010 of the EURL-FCM were accepted on 26.09.2009.

2.1.2 Documentation services, internal and external communication, interchange of information

To insure necessary information exchanges made between personnel of the EURL and/or between EURL personnel and partners and to manage external communications. Regular updates to NRLs were about monthly on average including for circulation of the documents and technical reports; updates on progress were monthly.

2.1.3 Ad-hoc questions or exchange of information with NRLs

Requests were met timely.

2.1.4 Technical and scientific support to the commission (EURL context)

NEW ITEM: support the Commission in the ongoing discussion on Plastic Implementing Measures and in particular on the revision of Community Guidelines for Migration Testing.

At the beginning of the year it was agreed between DG SANCO and the EURL to create a dedicated expert group in order to support the Commission in the ongoing discussion on Plastic Implementing Measures and in particular on the revision of Community Guidelines for Migration Testing. This represented a change in programme (additional item grafted onto the temporary completion of the guidelines on testing conditions and the guidelines on method development) and substituted the planned task forces on active packaging.

Three ad-hoc expert workshops were held on 1-2 April 2009, 29-30 June and 05 October to discuss and brainstorm the drafting of the DG SANCO Community Guidelines on migration testing in the context of the recast of the plastics directives into a Plastics Implementing Measure (PIM). The major deliverables were the drafting of two versions of Tehnical guidelines based on the original compilation of articles from DG SANCO (document referred to as EMB 1138). Comments and ideas from the NRLs were collected and compiled in a first version of technical guidelines. This first version was produced and was then presented during a DG SANCO working group with Member States. A second version was produced including flow chart to navigate testing for Overall and Specific Migration. Finally the EURL produced a compilation of data on fatty acid (FA) distributions of vegetable oils and recommendations for the technical criteria of FA profiles that could be given for simulant D2. This contribution was endorsed by NRLs and further DG SANCO.

The detailed topics discussed and respective outputs can be found in Annex 5.

2.1.5 Organisation of 2 plenary workshops

The two plenary sessions including their workshops were completed (plenary of July to develop the work programme 2010 and December to organize the practical planning).
The EURL-FCM held its plenary on July 1-2 2009 which focused on strategic and technical specifications of the ILC exercises for 2010. It reviewed the achievement and progress of the first half 2009.

The EURL-FCM held its December meeting took place to highlight the 2009 deliverables achieved and the practical implementation of the 2010 Programme.

2.1.6 Organisation of 2 special workshop (two with 2 items: 4th amendment and technical guidelines for the new PIM of DG SANCO)

Completed – Note: changes were made to make space for the work item on Community Guidelines which caused a delay on the work item active and intelligent packaging.

EURL-NRL expert workshop on drafting of Technical Guidelines for migration testing.
01/04//2009
The EURL-FCM held a special expert workshop to involve the FCM NRLs in the drafting of the technical guidance that will accompany the recast of plastics Directives, and it was found

that the 2 EURL guidelines (test conditions and method performance) could be a reference in a number of instances inside these guidelines. DG SANCO and MSA CA have highly welcomed the EURL initiative and this new type of work shifts also positively the EURL-FCM into a added value into anticipation of policies.

EURL-FCM ad-hoc workshop of working groups with its NRL network. 05-06/10/2009
The meetings focused on several items of technical issues relevant to implementation of legislation, including criteria for acceptance of the new vegetable oils simulant D2 (in the context of the Recast of plastics directives). The first edition of the method performance guidelines and Test Conditions guidelines were completed and published as EUR. The guidelines towards enforcement 4th amendment for official controls have also been completed and are to be officially closed at the December plenary. The second day focused on active packaging to consider the new Regulation, EFSA guidelines, raise unclear points and propose solutions to address them.

2.2 Quality assurance and control

To maintain the quality system set up according to the requirement of ISO 17025
To assure the continuous control on operational qualification of the personal, involved in accreditation process.

Successful renewal of Accreditation 17025, 19-20.01.2009 For the 6th consecutive year, the Community Reference Laboratory for food contact materials and BEVABS (Wine authenticity) laboratories successfully passed the External Audit and Official inspections for the Accreditation norms ISO/IEC 17025:2005 and ISO 9001:2008. This is an ongoing dynamic process successfully accomplished by the Unit Physical and Chemical exposure for its Quality System and a deliverable of a legal requirement for the EURL-FCM.
Renewal of ISO 9001 certification of the JRC/IHCP/CAT unit 05.03.2009 The Chemical Assessment and Testing Unit has obtained the renewal of the ISO 9001 certification complying with the latest edition of the norm (ISO 9001:2008) by the Italian certification body CERMET
Participation in ring trial Jan-March 2009 The EURL-NRL successfully passed another proficiency test organised by FAPAS, the UKAS accredited commercial scheme on overall migration from a plastic film. The results and report showed a very good z-score of 0.5 (close to the robust average) while the overall % of laboratories achieving z-score of less than 2 were only 73%. The test is part of the constant staff qualification testing in the context of the accreditation and QA system of the EURL, as well as self check for proficiency as official trainers for third country experts and staff from other NRLs
Participation in FAPAS proficiency test on migration of Bisphenol A in foods by the EURL-FCM March-May The EURL-NRL participated in a proficiency test organised by FAPAS, the UKAS accredited commercial scheme on quantification of Bisphenol A both in an oil and also a simulant for milk formula. The test is part of the constant staff qualification testing in the context of the accreditation and QA system of the EURL, as well as self check for proficiency as official trainers for third country experts and staff from other NRLs
Customer Satisfaction survey launched – April 2009

End

European Commission

Joint Research Centre – Institute for Health and Consumer Protection

Annex 1- detailed milestones for the work item 4th amendment

Milestones
EURL-FCM working group on EC/2002/72 4th amendment - 02.04.2009 The EURL-NRL FCM working group met to progress on a guidance document on specific issues related to the technical implementation of the 4th amendment of Directive 2002/72/EC. This meeting of the task force focused on 1) the Excel file calculating the acceptable substance concentration in fatty food simulant (D2) and in fatty foods made by Mr. Petersen (NRL-DK) based on the table of Mr. Kappenstein (NRL-DE) and 2) the guide addressing functional barrier-containing materials. Progress was reported in the specific technical reports. The new draft document will be circulated among all NRLs with the question to comment with a deadline of two weeks before the next TF on the 4th amendment.
2nd meeting 2009 of the 4th amendment Working group. - 29.06.2009 The meeting focused specifically the fat reduction factor (FRF). The FRF is a factor between 1 and 5 by which measured migration of lipophilic substances into a fatty food or simulant D and its substitutes shall be divided before comparison with the specific migration limits. This can be applied to the migration of specified substances. The EURL presented a series of flowcharts to illustrate the application of the FRF to migration data with the aim to arrive at a common understanding how to interpret the amended Directive applying the FRF. The FRF is only applicable for foods containing >20% fat. It was noted that the FRF is not applicable to overall migration. The flowcharts were corrected on two aspects. Firstly, Annex 1 point 2b.(a) of the amended Directive was clarified; the DRF is not applicable when the mass of the substance that migrated into simulant D is higher than 80% of the total mass of the substance in the finished material or article. Secondly, the restriction M(FRF) < 60 mg/kg is not correct but should be M < 60 mg/kg (by definition if the M(FRF) of a substance is less than its SML it is less than the 60 mg/kg). When results are presented on an area basis, i.e. containers less than 500 ml or more than 10 l and films/sheets, then the FRF is not applicable. A spreadsheet to calculate the FRF and total reduction factor (TRF) = DRF x FRF, drawn up by members of the 4th amendment task force, was presented. The aim was for this tool to be available on the EURL-FCM website. Based on the outcome of the discussion the spreadsheet was corrected. The new spreadsheet will contain worked examples showing all possible situations according to the flowcharts. The document provided on the functional barrier was briefly reviewed. The document is intended to be used by food inspectors and therefore it should highlight the questions that they should ask for a company to provide evidence in support of the presence of a functional barrier. This information should be included in documentation relating to the Declaration of Compliance.
October meeting - 06.10.2009 The document ”Enforcing the Phthalate regulation in fourth amendment.doc” which gives an interpretation of the text as to which limit should be applied to which phthalate and in which application was considered ready for publication. The document on functional barriers was discussed. The intention is for this document to be used by food inspectors and enforcement laboratories to ensure that the correct information is obtained to allow the assessment of a claim that a given layer acts as a functional barrier. This information should be included in documentation relating to the Declaration of Compliance. The meeting agreed that this document was ready for publication after including some final comments of Mr. D’Atri (DG SANCO). The FRF was discussed. A series of flow charts were presented that illustrate the application of the FRF to migration data and an excel spreadsheet was also presented. Correction for the application of the real and experimental surface area to volume ratio was included. It was concluded that the flow charts represents how an experimentally obtained specific migration shall be corrected under the various conditions mentioned in the amended Directive 2002/72/EC before it is compared with the specific migration limit. However, the meeting advised to make the flow charts more user-friendly in the future. The presented version of the excel spreadsheet included all the needed formula’s. However, to be more user-friendly Mr. Hoekstra (EURL) indicated that it will be improved in such way that the user will get one answer on the maximum acceptable concentration or migration in the experimental conditions after introducing all the input parameters. An overview of the activities of this Task Force was drafted for inclusion on the EURL website. Another discussion point was the change in the reporting of the migration of primary aromatic amines. Prior to the implementation of the 4th amendment to Directive 2002/72/EC the limit defined for the sum of non-listed PAAs was given as 20 µg aniline equivalents per kg of food or food simulant. In the 4th amendment this changed to 10 µg per kg of food or food simulant. Therefore the conversion to aniline equivalents is no longer required when demonstrating that the detection limit of the method is compliant with this restriction. Mr. Petersen (NRL-DK) agreed to draft text for inclusion in the overview document on the 4th amendment for inclusion on the EURL website. Mr. Hoekstra (EURL) reminded the participants that the above mentioned documents need regular updating accommodating the experience of the enforcement laboratories using them. The guidelines towards enforcement 4th amendment for official controls were considered completed and will officially close at the December plenary.
Plenary meeting - 02.12.2009 Flow chart The EURL showed and illustrated for all NRLs the flow chart summarising the actions to be done, when planning a full analysis process, prepared in collaboration with NRL-DK The participants discussed the flow chart with the EURL and DG SANCO. Some modifications were further introduced for completeness and or user-friendliness, for example the introduction of a decision box for testing with food simulant A, B, C, 50% EtOH. An explanatory note will be prepared including some examples that follows the flow chart with coloured lines A more generic title of the flowchart will be formulated. The scope of the spreadsheet was made broader so it can be used for comparing all experimentally obtained migration results. It was presented and illustrated by the EURL. Some participants reported some difficulties in using the sheet, and some confusion. It appeared that these problems were not structural on the content of the spreadsheet itself, so EURL proposed to solve these problems bilaterally. NRL-DK reported that NRL-PT found the part called “calibration, revised” confusing. This will be changed. NRL-IT proposed to add a small note or document to explain the proper use of the excel sheet (with links to the related parts of the legislation), which can also help NRLs to explain and train their own local laboratories. The EURL proposed to add also an example that can be the same on used for the flow chart. It will be a combined explanatory note with the previously discussed flowchart. NRL-IT proposed to check for some possible errors that can rise when using it. EURL proposed to correct what has been found so far and publish it. Additional comments or issues should be then reported to the EURL for further updates for improvements. All participants agreed. The EURL will update the spreadsheet with the changes and publication on the Circa web site Regarding the analysis of primary aromatic amines, a correction to the document was made on the molecular weight of MDA being twice that of aniline. The calculation of the example according to the new situation was adapted. NRL-DK raised the issue of performance of methods and provision of method standards for the analysis of PAAs, when more than 5 PAAs are analysed. The EURL gave some information and update regarding the completed validation of methods for PAAs that was done by BfR and the chairing of the CEN groups having gone to DTU (DK, Mrs. Pedersen). The overall document was considered finalised and correct.

Annex 2: The detailed milestones of the work item 1b2-1 on interlaboratory comparison for the measurement of DIDP in oil are summarised in the table below:

Progress and / or Milestone	Timeline
Launch of questionnaire on methods for DIDP prepared by NRL-UK and as well as an example already filled out	16.12.2008
Preparatory phase: Analysed stability of sunflower oil source, Designed and purchased smaller size mixing devices for oil matrix Development of questionnaire on methods of analysis of DIDP from the 2008 exercise. The questionnaire was developed based on the contribution of NRL-UK with a standard format also applied in the FAPAS scheme the tailored further by the EURL for the generation of specific information on standard operating protocols (SOP) used by NRLs for the EURL-FCM PT 2008 of plasticizers including DIDP.	Jan- Feb
Reminder for questionnaire - deadline: January 30th	21.01.2009
Sending for info the IRMM report on phthalates. Third and final reminder for sending the questionnaire on DIDP method extension of deadline to Feb 13th.	05.02.2009
Collection, compilation and tabulation of results Generation of SOP based on the results: Based on the answers of the questionnaires, the EURL progressed both with drafting of a method description for DIDP as well as with in-house method comparisons when there were several options. The EURL completed this phase and had therefore the description as proposal, where one can also see in boxes the reasoning or background for choices. Sending of SOP for review and consultation: an agreement on the method description was requested no later than April 17 2009. In case the EURL did not receive a response by that date the EURL would consider it a tacit agreement.	March-April 03.04.2009
Further Desktop and experimental work on SOP: Update of April to NRLs reported that the SOP was finalised with the information as well on progress on preparation. 3 solvent solutions and blank as well as the oil matrices (3 levels and blanks) were prepared; the EURL was conducting the homogeneity testing. The shipment was expected therefore early June. Launched of consultation of resulting SOP, with consultation on choice of internal standards Further comparative experimental test on possible variations of SOP based on comments received as well on method performance using different internal standards Preparation of revised SOP including notes on parts tested for variations and their results Further consultation and consensus collected for final SOP to test Final SOP discussed briefly for final endorsement in plenary	May-June
Preparation of the oil reference materials containing DIDP for the method validation interlaboratory trial . Completion of preparatory tests for production of fortified oil, Tests on matrix mixing devices: PASS Production of fortified oil DIDP at 4 different levels Ordering of the selected internal standard (30 vials) to include its provision free of charge to the NRLs as consumable. Note: unexpected delays rose in the full delivery from the supplier. The NRLs were informed and consulted on the options that included the separate shipping of the internal standard by rapid courier. To expedite the process, it was also ultimately decided in agreement with the NRLs to opt for the EURL providing a stock solution when the supplier informed of additional delays for the final delivery of the full number of vials. Homogeneity testing of spiked DIDP matrices at the 4 concentrations Purchase shipping materials (boxes, vials, protective wrap etc) and Subsamples test materials into test kits Completion of all homogeneity testing on DIDP in oil : PASS Launch of stability of DIDP in oil	May-June
Launch of 1st comparative trial 2009 (method validation) on DIDP in oil by the EURL-FCM Shipment to NRLs of 4 sets of oils corresponding to 4 levels of concentrations and a blank. Together with instructions, invitation and confirmation of participation forms, confirmation of receipt of samples forms, and shipment details shipped Action requested: 4 replicates results for each substance – report requests for participation of more labs.	15.06.2009
Discussion in the plenary: The EURL was still awaiting delivery of the labelled internal standard which it will provide to the NRLs. Therefore it was agreed that the timing of the trial should be put back with delivery of the results by 11th September (delayed from 31st July). Some laboratories had already tried the method and reported problems with the separation of the oil and the solvent phases. Additional detail will be tested in the laboratory and the outcome added to the SOP and the revised version will be sent by e-mail by the EURL.	01.07.2009
ILC: Confirmation of Deadline for all tests: 11.09.2009 The software forms and instructions for the reporting of the results were sent by e-mail	08.07.2008
The EURL completed the distribution of the materials towards the exercise on diisodecyl phthalate (DiDP) for the EU validation of a method for DIDP in oil	08.07.2008
Closing of the exercise	11.09.2009
Statistical interpretation	10.2009
Presentation and draft report	01.12.2009
Final report	30.03.2010

Annex 3: The detailed milestones for the work item 1b2-2 on the validation of BPA are summarised in the table below:

Progress and / or Milestone	Timeline
Preparatory phase: Search for materials for a phase on migration testing. The EURL obtained the collaboration of CEFIC for producing PC test materials. From a physico-chemical and production standpoints, it was not feasible to produce "high releasing" materials. A lot of technical exchanges took place with the CEFIC - FCA, PC subgroup. Prototype materials were expected towards the middle of April. Communication to NRLs on progress on materials (March update) From a validation standpoint, The EURL informed the NRLS that it was most advisable to run the validation of the quantification method and the migration method concurrently, so that the EURL was held back to await for materials and running some comparative tests on them to evaluate if the EURL can have measurable migration and also perform the homogeneity testing. So the EURL may have a timeline where samples are sent not before July and a deadline for results in September (worst case would be early September and results mid October).	Jan- Feb 03.04.2009
Update NRLs of April The EURL received the third of 3 batches of different PC via the CEFIC PC group. the EURL was now conducting t/T test to estimate release (if and when measurable, for example) and conduct preliminary tests.	15.05.2009
Preparation of the 50% Ethanol stimulant containing BPA for the method validation interlaboratory trial. Completion of preparatory tests for production of matrices: Tests on matrix mixing devices Production of fortified 50% Ethanol containing BPA at 4 different levels Homogeneity testing of spiked BPA matrices at the 4 concentrations Purchase shipping materials (boxes, vials, protective wrap etc) Subsamples test materials into test kits Completion of all homogeneity testing on BPA in 50% Ethanol : PASS Launch of stability of BPA in 50% Ethanol	June- July
The EURL reported a situation in a special e-mail communication and involved its NRLs for input: The EURL received via the industry associations 3 separate tentative BPA-containing PC as reference materials (RM); these were pieces of approx. 4x6cm, therefore to be tested by immersion. The minimum volume for upright immersion would lead to about 0.5dm2/100ml. The EURL performed a preliminary test of 2hr70C (once) and 10 days 40C (once); The results showed that 2 RMs showed an interfering peak with BPA, and all materials did not release detectable levels when tested at 2hr 70C. When tested at 10d 40C the third material released at 1 g/L (the second was lower and less homogeneous). Tests were also conducted by cutting the material in two sub pieces to get 2 g/L. As conclusion the highest "release' the EURL could hope for would be using 10d 40C (or even more drastic) and by increasing the S/V ratio in order to be in the range of 2ppb. This would in turn mean that the validation of conventional test conditions is not feasible (3 times 2hr 70C cannot be validated since it was non detectable). A number of options were thus proposed by the EURL: 1) the EURL does not validate the migration test at all 2) the EURL conducts an interlaboratory exercise only with some NRLs as volunteer laboratories using the set up of 10d40C to estimate the uncertainty of a migration measurement at the LOQ level. 3) the EURL adds a concentration step to the protocol 4) the EURL changes the method entirely to a GC_MS derivatisation with a [d16] BPA standard to have higher sensitivity (so that 2ppb would be significantly higher than LOQ) 5) the EURL switches – for the part on the material- to the validation of a method for residual content (e.g. QM type measurement) Inputs were collected until June 23rd in order to discuss at the plenary.	15.06.2009
Update June NRLs and Discussion in the plenary The EURL reported the preliminary analyses made that showed that all materials could only release Bisphenol A at levels no greater than the limit of quantification (LOQ) when tested using the appropriate combination of simulant, test time and test temperature. A number of options were proposed by the EURL first by e-mail of the update May-June on June 15 (7 answers received) and again during the plenary to cover all MS NRLs. From the 5 previous options, the 3 main ones were discussed. 1) the EURL could carry out the test on spiked 50% ethanol only. 2) the EURL could carry out the test on spiked 50% ethanol and the EURL conduct an interlaboratory exercise on the polycarbonate test material using test conditions of 10 days at 40°C (or more harsh conditions) to get an estimate of the uncertainty of the migration measurement at the LOQ level. 3) the EURL could carry out the test on spiked 50% ethanol and the EURL carry out a research based study to investigate the effect of storage between repeat exposures on the migration using conventional simulants, exposure times and exposure temperatures associated with the use of polycarbonate as baby feeding bottles. It was agreed that for the EURL 2009 programme the work would be restricted to option 1. However rather than just validating the method at levels close to the SML (0.6 mg/kg) as required for compliance purposes and to provide the validation data for inclusion in the CEN standard, it was decided that a second validation range would also be studied to allow validation data to be generated for exposure purposes. In total four 50% ethanol solutions containing different concentrations of Bisphenol A were provided for analysis encompassing concentrations of relevance to exposure determination and compliance determination. Standard operating procedures for the two approaches would be written. Mrs Simoneau explained that they have been asked to collate all data on migration of Bisphenol A. All NRLs were asked to send the results of the work that they have carried out on this topic to the JRC.	01.07.2009

Launch of the 2nd comparative trial 2009 (method validation) on BPA in oil by the EURL-FCM The EURL-FCM completed preparation and homogeneity testing of four 50% ethanol solutions containing different concentrations of Bisphenol A. These were provided for the validation of a method of analysis on the new milk simulant and to in addition encompass concentrations of relevance both to exposure determination and to compliance determination. The samples and SOP(s) were sent and the deadline for the submission of results was mid-October. 4 sets of simulant corresponding to 4 levels of concentrations and a blank were shipped to NRLs together with instructions, invitation and confirmation of participation forms, confirmation of receipt of samples forms, and shipment details. Action requested: 4 replicates results for each substance – report requests for participation of more labs.	20.08.2009
ILC: Confirmation of Deadline for all tests: 12.10.2009 The software forms and instructions for the reporting of the results were sent by e-mail	27.08.2008
Closing of the exercise	30.10.2009
Statistical interpretation	01.11.2009 on
Presentation and draft report	01.12.2009
Final report	30.03.2010

Annex 4: Detailed deliverables of the deliverables related to the EURL or activities of representation for the EURL-NRL FCM Network.

Publications as JRC Technical Reports:

Milestone
Annual Activity Report 2008 of the Community Reference Laboratory for Food Contact Materials [SANCO/2008/FOODSAFETY/0047-Contact Materials], SIMONEAU Catherine 2009 EUR Number 23973 EN ISSN 1018-5593; 1831-1822 ISBN 978-92-79-13160-8 Catalogue Number LB-NA-23-973-EN-C DOI 10.2788/30574.
Report of the first interlaboratory comparison organized by the Community Reference Laboratory Food Contact Material: Plasticisers in Gaskets and Oil. BRATINOVA Stefanka , VALZACCHI Sandro, BELDI Giorgia, MORKUNAS Vaidas, CONTINI Claudia, HANNAERT Philippe, SIMONEAU Catherine. 2009 EUR Number 23972 EN ISSN 1018-5593 ISBN 978-92-79-13159-2 Catalogue Number LB-NA-23-972-EN-C DOI 10.2788/29683 This report presents the results of the ILC of the EURL-FCM which focused on the determination of Plasticisers content in PVC Gasket and in Oil matrix. The test materials used in this exercise were virgin gasket lids coming from industrial sources for the proficiency exercise part A. For the second part of the exercise an industrial source of sunflower oil was used and spiked with several plasticisers by the EURL-FCM. There were 41 participants to whom samples were dispatched 34 of which submitted results for at least 1 analyte-material. 21 laboratories reported results for more than 10 analyte-material combination out of 14 required.
Guidelines on testing conditions for articles in contact with foodstuffs (with a focus on kitchenware) - A EURL-NRL-FCM Publication, 1st edition 2009, SIMONEAU Catherine. 2009 EUR Number 23814 EN ISSN 1018-5593 ISBN 978-92-79-12261-3 Catalogue Number LB-NA-23814-EN-C The harmonisation of test conditions are crucial to obtain reliable results for official controls. For plastic food packaging time/temperature conditions are specified in Directives, but kitchen articles are placed in contact with food in the home, and Rapid Alerts have shown differences in testing in enforcement protocols. The guidelines just published describe worst foreseeable test conditions for food contact articles such as kitchenware. They represent a reference consensus for NRLs to better ensure harmonisation of official controls and are a major deliverable of the mandate of the EURL-FCM.
Completely harmonised to corporate standards and full of easy to find information, the new web site for JRC and EURL activities on Food Contact Materials was launched. This was a deliverable of the EURL workprogramme.
Guidelines for performance criteria and validation procedures of analytical methods used in controls of food contact materials. A EURL-NRL-FCM Publication, 1st edition 2009; Bratinova, S., Raffael, B., Simoneau, C. 2009 EUR 24105 EN. ISBN 978-92-79-144-7. ISSN 1018-5593; DOI 10.2788/49046 Luxembourg (Luxembourg): OPOCE; 2009. JRC53034 Article 32 (1b) of Regulation 882/2004 on official feed and food controls addresses comparability as the most important feature of the measurements of National Reference Laboratories. A fundamental step in the implementation of performance and harmonization the evaluation of method performance, which was lacking until now for the field of FCM. The impact was an improvement on the quality of methods used by official controls, and therefore a better implementation of the Regulation on official feed and food controls for the field of FCM. Based on a series of workshops with a NRL-FCM dedicated working group, the EURL_FCM developed the first official harmonized guidelines for the validation and evaluation of method performance. The final product was published as (EUR 24105 EN -2009) in support to the implantation of Regulation 882/2004.

Scientific works

2 Abstracts submitted to conference 4th International Symposium on Recent Advances in Food Analysis (RAFA 2009)..

Study of the migration of photoinitiators through the vapor phase. A.Rodríguez-Bernaldo de Quirós, R. Paseiro-Cerrato, S. Pastorelli, R. Koivikko, C. Simoneau and P. Paseiro-Losada.

Rapid multianalyte quantification of benzophenone, 4-methylbenzophenone and related derivatives from printed paperboard food packages. R. Koivikko, S. Pastorelli, A. Rodríguez-Bernaldo de Quirós, R. Paseiro-Cerrato, P. Paseiro-Losada, and C. Simoneau

Invited presentations

Presentation to the Annual Plenary of the International Organisation for Vine and Wine, 19.03.2009

C. Simoneau was invited presenter to the Annual Plenary of the International Organisation for Vine and Wine on the "Role of JRC and EURL-FCM in analytical developments and standardisation for compliance testing and official controls on food contact materials". It provided a strong message of the link from quality to food safety for the wine sector, in particular for potential concerns related to FCM such as cork, wood, plastics ("bag in the box"), phthalates, and epoxy from containers. Collaboration was offered towards the drafting of future methods (e.g. support to 479/2009).

Presentation on food contact safety to the IPACK-IMA packaging and processing convention, 25.03.2009

C. Simoneau was invited to present the role and achievements of JRC and EURL-FCM and its importance in emergencies to the conference IPACK IMA, a major conference on Processing, Packaging and Material Handling. IPACK IMA is one of the most influential event for suppliers of food and non-food technology and trade buyers. The presentation took place in the context of a special convention event "Safe Packaging = Safe foodstuff: Plan the future. Packaging is quality of life" organised for all stakeholders by the Italian packaging institute. About 100 participants attended and showed high interest.

Presentation on EURL-FCM and information exchange with EURL-PAHs and EURL-mycotoxins, 20.04.2009

C. Simoneau was invited to present to the IRMM Seminar series the work done by the EURL-FCM including in the area of reference materials and measurements and metrology such as comparative testings and validation of methods. The Seminar was followed by a specific meeting with T. Wenzl (EURL-PAHs) as well as J. Stroka and A. Breidbach (EURL-mycotoxins) to discuss areas of common interests and harmonisation of practices for to strengthen closer collaborations and exchange of information.

Presentation on EURL-FCM, 28.04.2009

B. Raffael presented "European Reference Laboratory for materials and articles intended to come into contact with foodstuffs" at the 17th VFV Lecture "Trends in the field of European Food Packaging" on 28 April 2009, Aschaffenburg, organised by the institute ISEGA Forschungs- und Untersuchungsgesellschaft mbH.

Presentation to Scientific Tea on quality management., 13.05.2009

C. Simoneau, S. Tirendi, S. Cordeil and M. Mazzara gave presentations to the scientific tea "Quality for Science: what's in it for you?". The question raised was what is the added value for both the organisation but also for scientists of implementing a Quality Management System in a scientific environment. The speakers from IHCP Units all had already implemented a Quality System. The discussion revolved around both the Quality Managers and the Scientific Officers viewpoints that talked about their own experiences about, the extent of the results achieved and what it took to get there. The event attendance and questions was a success.

Keynote presentation to the Brokerage Event of the EU project Safetechnopack, Istambul, 04.06.2009

C. Simoneau was invited as keynote speaker to the Brokerage Event of the EU project Safetechnopack. The event aimed to increase the relations between the industry, universities, and research centers operating in food packaging. The event was a success with almost 100 participants. JRC is both on the advisory board as well as the main training facility. This collaboration is an important contribution of active participations in capacity building EU RTD projects as mentoring expertise, and within the collaboration agreement between JRC and Tubitak.

Conference: Traçabilité et sécurité alimentaire en Italie et en France "La sécurité dans l'assiette", 16.06.2009

C. Simoneau was invited as speaker to this event, with A. Zenie contact co-organisor. This event was a JRC-IHCP, Camera di commercio di Milano Chambre Francaise de Commerce et de l'industrie joint initiative.This innovative event aimed to increase the relations between the industry and institutes in the area of food safety. The event was a success with almost 80 participants attended the sessions and the afternoon of interactions.

Presidency of the Journee Technique de l'emballage; Paris, 18.06.2009

C. Simoneau was invited to preside the day, with introductory keynote address and moderating the event. This 4th event gathered professionals of Packaging, technical and quality management around key issues on Statutory matters, hygiene and innovation, in line with needs and market evolution. The event gathered more than 80 participants with industrial stakeholders as well as associations, and was organised by the LNE (laboratoire National d'Essai et de Metrologie), which is a National Reference Laboratory for France.

Main visits

Visit of Communication and Media Relations of Helmholtz Association of German Research Centres to the EURL-FCM, 25.03.2009

Mrs. Effrosyni Chelioti, Communication and Media Relations for the Helmholtz Association of German Research Centres, chose to visit the activities on food contact materials as selected visit for IHCP. The Helmholtz Association is Germany's largest scientific organisation (28,000 employees in 15 research centres) and contributes to solving major challenges facing society, science and industry with top scientific achievements in six research areas: Energy, Earth and Environment, Health, Key Technologies, Structure of Matter, Transport and Space.

DG RTD to FCM activities, 11.05.2009

The head of unit of Food Safety visited the activities on food contact materials. He was particularly interested in the success of the RTD project foodmigrosure into the current development of changes in the legislation.

Open day JRC 50th anniversary, 16.05.2009

Many IHCP activities participated in as exhibitors, e.g. Indoortron and food contact materials. Indoortron had the chamber set up as living room and experiments on smell, and food contact materials showed a short movie, followed by explanations in a walking exposition that ended in an interactive areas with learning games. The themes covered the development of packaging and its materials, with an emphasis on plastics, testing the safety of foods, recycling processes and how to recycle better. There were more than 1000 visitors to the FCM activities as shown by the number of questionnaires.

Visit of the school "Istituto Di Tozzi, Cugnoli" Abruzzo , 23.10.2009

12 children 7 parents and 2 teachers came to visit the EURL FCM. In the context of visit to the whole JRC. The EURL-FCM was the activity chosen for the IHCP. The 4th graders had the chance to see a short movie and have interactive show and tell on the work, the experiments and the instruments used to test food packaging and food utensils. They also could see the projects submitted by other schools in the context of the 2009 competition "scuola e creativita"

Annex 5: The detailed topics discussed and respective outputs from the workshops regarding technical guidelines in support of the Plastic Implementing Measure.

The major deliverables of the 1st meeting were:

- Overall migration: volatiles could be dropped
- Vegetable oils: were found a good improvement; the characteristics (specifications) should be more targeted to the extractive power, e.g. acidity (maybe), C16/C18 (because in CEN standard for OM), and profiles of fatty acids or triglycerides.
- Repeat use articles: 1st test results should be considered for substances with a non detectable limit
- The hierarchy of tests should be clarified screening/substitute test, verification as well as the 'analytical tolerance'.
- The exemptions to test with substitutes instead of vegetable oils should be clearly laid out (for migration, not screening). As follows: swelling, technical problems (e.g. volatiles, unstable substances), oil extraction problem and/or problem of interferences (e.g. fatty acid esters, FAME)

A first version of the guidelines was discussed based on the original compilation of articles from DG SANCO (document referred to as EMB 1138). Comments and ideas from the NRLs on the draft Community guidelines on migration testing of plastics were collected and compiled in a version of technical guidelines. This first version was produced and was then presented during a DG SANCO working group with Member States.

The EURL-FCM held a 2nd special working group with the NRL network for FCM. The scope of the 2nd ad-hoc expert workshop was again to discuss and contribute to the drafting of the DG SANCO Community Guidelines on migration testing in the context of the recast of the plastics directives into a Plastics Implementing Measure (PIM). A first draft drafted by the EURL was presented for review. The specific goals were and set the road maps of the tests for migration as well as their hierarchy in testing schemes.

- Establish the flow charts and hierarchy of methods
- Establish the format of some tables presented into the technical guide.
- Establish worked examples.
- Discuss introduction
- Discuss some points and flow or structure of the guidelines.

A second version was produced and further amended following further specifications obtained during the DG SANCO working party meeting of 13 July.

The scope of the 3rd meeting was to review the technical criteria for acceptance of the new vegetable oils simulant D2 (in the context of the Recast of plastics directives). The PIM will specify the use of a possible range of vegetable oils rather than olive oil as simulant D2. Without specifications on the characteristics of the vegetable oils then any oil could be used. Several types of criteria could be used as technical specification either for quality or chemical parameters. These parameters likely came from Codex Standards for oils. There are a significant number of sources of vegetables so criteria should be set as umbrella of compositional acceptance for use as media for testing migration. Criteria of most relevance can be the fatty acid profile as this will differ with different oils. This could be expected in turn to result in differing degrees of interaction between the polymer and the oil and different solubilities of migrants in the oils. It is possible that an increase in the degree of unsaturation of the fatty acids may result in a –relatively- more polar oil which may be expected to influence the migration of individual substances. To the best of the EURL and NRL's knowledge there was very little data comparing the migration into different oils. The EURL mentioned a study by Grob et al. on PVC as the only example found so far. In the absence of such data it was proposed that the fatty acid profile of the oils should be specified in the legislation and that this should be relatively restrictive until data is available to support the inclusion of other oils with other fatty acid profiles. The profiles proposed by the

Commission and eventual revised proposals by the EURL were given in an accompanying document 'Simulant D2 composition_V1.pdf'. It was agreed that any specification should cover the profiles from olive oil to sunflower oil as these were previously allowed. The NRLs raised the point that the Peroxide value specified for olive oil may be met at the time of purchase but once open oxidation of the oil will occur. Similarly during a 10 day exposure the oxygen level in the oil may be expected to change. The Sample preparation for reconstituted foods was also discussed. The conclusion at the last meeting was that clarification was required in the PIM as to whether the migration should be reported based on the food mass taken from the packaging or based on the mass of the foodstuff following reconstitution or concentration. Examples discussed were infant formula and fruit cordials that are diluted prior to consumption and dried pasta which takes up water during cooking thereby altering the mass of the product. Examples of concentration of the sample were primarily in food processing for example in the manufacturer of sauces and pastes. It was agreed that the EURL should contact the Commission to confirm what this paragraph means and that they should provide examples of the different scenarios that may be foreseen and what the different outcomes would be with respect to compliance with the legislation.

Annex 6: Technical assistance in support to Member States and Technical Meetings

This item is presented here as it is a cross over between the role as EURL and the role as JRC.

DG SANCO working party of Member States Competent Authorities on food contact materials, 20.02.2009 C. Simoneau participated to the SANCO Member State competent authorities to intervene on a number of issues. One was to report on technical questions related to the project FoodMigrosure in the context of the consequent recast of the Plastics Directive. Following the issue of non authorised 4-methyl benzophenone found in breakfast cereals from UV cured inks from cardboard boxes in February and led to notifications in the RASFF system, the JRC provided emergency actions to Member States official controls. C. Simoneau gave an update on the analytical methods of analysis and an outcome was for the EURL-FCM to make all methods available to the public on a special web page. A new web page assisting crisis testing of Benzophenone in food contact materials was thus created and the first 24 hrs registered 2000 hits. The EURL-FCM also provided the data to EFSA and in support to the drafting of an emergency exposure assessment opinion which was successfully published on the 3rd of March with acknowledgements. These are milestone both as EURL in support to the correct implementation of food official controls policies as well as a milestone in the context of the current collaboration agreement JRC-EFSA.
DG SANCO working party of Member States Competent Authorities on food contact materials April 2009 (6-7.04.2009) C. Simoneau participated in the Working Group of DG SANCO for Food Contact Materials. The group which is comprised of 10 experts worked on the future directive revising and codifying legislation related to plastics, as well as discussing a proposed merging technical specifications into guidelines rather than Directives. The contribution included conveying the test conditions also discussed in the TF NRL FCM on test conditions as well as other technical issues. C. Simoneau also participated to the SANCO Member State competent authorities b in the context of the consequent recast of the Plastics Directive. On the issue of 4-methyl benzophenone found in breakfast cereals that led to notifications in the RASFF system, she gave an update on the analytical methods of analysis, provision of reference substances by the EURL-FCM and monitoring of use of the special web page.
DG SANCO working party of Member States Competent Authorities on food contact materials. 19-20/05/2009 On 19.05.2009 C. Simoneau was invited to act as technical and Commission expert to a special technical meeting on the recast of the plastics Directive. The meeting focused on the changes introduced by the recast in testing migration. The 3 technical experts were present to explain the scientific basis for the changes and where the changes introduced a simplification or a complexity in testing and why. On 20.05.2009 C. Simoneau participated to the Member State Competent Authority meeting of DG SANCO on food contact materials. The meeting scope was also the recast of all directives on plastics into a single regulation this meeting focused on the changes in test conditions introduced by the recast. The results of the special technical meeting of May 19 were discussed. A question was raised on melamine and a Codex Alimentarius work item proposed for method for melamine to apply to all food at the level of 2.5ppm. This would have implication for food contact as the current test is only validated to 30ppm and also raised the question on whether the migration from foils and coatings would be in compliance. JRC informed that research was already undergoing with the collaboration of industry association to test laminates for migration with the scope to assess whether the CEN method could be adapted to calibration levels in the new range. JRC also mentioned that they also shared reference materials with FERA to compare methods as well as been in contact with IRMM to also discuss collaborations on that topic.
DG SANCO working party of Member States Competent Authorities on food contact materials July 2009 (08.07.2009 and 13.07.2009) On 08.07.2009 C. Simoneau was invited to act as technical and Commission expert to a special technical meeting on the recast of the plastics Directive. The meeting focused on the changes introduced by the recast in testing migration. The 2 technical experts were present to explain the scientific basis for the changes and where the changes introduced a simplification or a complexity in testing and why. On 13.07.2009 C. Simoneau participated to the Member State Competent Authority meeting of DG SANCO on food contact materials. The meeting scope was also the recast of all directives on plastics into a single regulation. This meeting focused on the changes in test conditions introduced by the recast. The results of the special technical meeting of July 08 were discussed. C. Simoneau as EURL will provide the technical guidelines to this new recast that the she developed has developed as an emergency topic for the EURL. This document is now ready and will be sent on July 15.
DG SANCO working party of Member States Competent Authorities on food contact materials 03.09.2009 C. Simoneau participated to the Member State Competent Authority meeting of DG SANCO on food contact materials. The meeting scope was the recast of all directives on plastics into a single regulation. This meeting focused on a new draft of the PIM based on the results of the agreements of the meeting of 13.07.2009. C. Simoneau intervened on several technical issues such as sample preparation for reconstituted foods and criteria for oils as simulants to summarise the viewpoints raised in the EURL-FCM plenary of 1 July 2009. A number of items will be thus raised in the next meeting EURL of Oct 5-6th.

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Abstract

The following report is a technical report mostly destined to Commission services, National Reference Laboratories and Member State Competent Authorities. It reports the 2009 update of the deliverables from the work programme 2009 of the European Union Reference Laboratory for Food Contact Materials established under Regulation EC No 882/2004. The 2009 annual work programme of the EURL included methods of analysis protocols (Art 32 1(a)), reliability of results & comparative testing (Art 32 1(b)), with several guidance documents produced on method performance and validation, on sampling and testing conditions, on the 4th amendment of Directive 2002/72/EC. Two validation studies for a) Di-isodecyl phthalate (DIDP) in oil and b) Bisphenol A (BPA) in the new milk simulant 50% Ethanol were organised and completed successfully. Other items completed included the collection of reference monomers and additives, emerging issues such as the Plastic Implementing Measures and in particular on the revision of Community Guidelines for Migration Testing, as well as on active and intelligent packaging (AIM). Several trainings were organised by the EURL upon request, including delegates from the FVO as well a for a delegate from Vietnam.

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